



NIPRO MEDICAL CORPORATION
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AUG 12 2009

510(k) Summary NIPRO® Disposable Syringe

807.92(a) (1)

Applicant: Nipro Medical Corporation
Establishment Reg.: 1056186

Contact Person: Jessica Oswald
Regulatory Affairs Specialist

Date of summary preparation: April 30, 2009

807.92(a) (2)

Trade Name: NIPRO® Disposable Syringe
Common Name: disposable syringe
Classification Number: 880.5860
Classification Name: Piston syringe
Panel: 80
Product Code: FMF

807.92(a) (3)

Legally marketed substantial equivalent device:
NIPRO Disposable Syringe (K944355)

807.92(a) (4)

Description of device:

The NIPRO Disposable syringe is a piston syringe consisting of graduated barrel, plunger rod, gasket and nozzle tip cap. Its function is mechanical and it is intended to inject fluids into or withdraw fluids out of the body. The syringe is sterile, single use only, non-toxic, non-pyrogenic and sterilized by Gamma radiation.

807.92(a) (5)

Indications for Use:

The Nipro Disposable Syringe is intended to inject fluids into or withdraw fluids out of the body.

807.92(a) (6)

Comparison of technological characteristics:

Nipro Medical Corporation considers the modified NIPRO® Disposable Syringe Gamma to be substantially equivalent to the current NIPRO® Disposable Syringe (K944355) with regard to intended use, materials of construction, labeling, and overall performance characteristics.

807.92(b) (1)

Non-clinical tests submitted:

Biocompatibility data, performance testing and comparison testing with the predicate are included in this submission and demonstrate substantial equivalence.

807.92(b) (3)

Conclusions drawn from non-clinical and clinical tests:

The results of the performance testing and the comparison of technological characteristics demonstrate that the NIPRO® Disposable Syringe Gamma performs equivalent to the predicate device and is safe and effective when used as intended.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Ms. Jessical Oswald
Regulatory Affairs Specialist
Nipro Medial Corporation
3150 North West 107th Avenue
Miami, Florida 33172

AUG 12 2009

Re: K091279
Trade/Device Name: NIPRO[®] Disposable Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: July 13, 2009
Received: July 15, 2009

Dear Ms. Oswald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

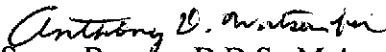
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: NIPRO® Disposable Syringe

Indications for Use:

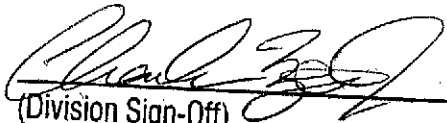
The Nipro Disposable Syringe is intended to inject fluids into or withdraw fluids out of the body.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use _____
(21 CFR 801 Subpart C)


(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

NIPRO® Disposable Syringe (Gamma)

510(k) Number: K091279

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